REMARKS

In the Office Action under reply, claims 1-4, 6-8, 26, 29, 46, 47, 101, 102, and 104-109 stand rejected. Claims 9-11 and 14-22 stand withdrawn as directed to nonelected species and claim 76 stands withdrawn as directed to a nonelected invention.

With this response, claims 1, 13 and 109 are amended, and new claim 110 is added. Accordingly, upon entry of this amendment, claims 1-4, 6, 7, 9-11, 13-22, 26, 29, 46, 47, 101, 102, and 104-109 will remain pending.

Applicants acknowledge with appreciation the withdrawal of the grounds for rejection and/or objection from the previous Office Action.

Reconsideration is respectfully requested in light of the above amendments and the following remarks. For the Examiner's convenience, Applicants' remarks are presented in the same order in which they were raised in the Office Action.

A. Amendments to Claims

Applicants amend claim 1 to insert the term "essential oil" in place of "mint oil." Support is found in the originally filed claims. Claim 1 is further amended to add a product by process limitation specifying: "wherein the sustained release matrix is formed by a process consisting essentially of admixing the micronized ethylcellulose and the essential oil flavoring agent at room temperature and ambient humidity." Support is found at Example 1, paragraph 00097 of the Specification.

Claim 109 is amended to depend from claim 1 and include the additional product-process step of "allowing the admixture of the micronized ethylcellulose and the essential oil flavoring agent to set and cutting the matrix to provide the lozenge." Support is found at Example 1, paragraph 00097 of the Specification.

Claim 110 is added to introduce the limitation of essential oil being a mint oil. Support is found in original claim 12, now cancelled.

Claim 13 is amended to depend from claim 110.

Amendments find support in the originally filed claims and are introduced solely to put all pending claims in allowable form. No new matter is added. Entry of the amendments is respectfully requested.

With respect to claim amendments, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and have not acquiesced to any rejections or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution on any presently excluded subject matter in one or more future continuation and/or divisional application(s).

B. Second Declaration under 37 CFR 1.132 by Jerry B. Gin

Applicants submit herewith a second Declaration by Jerry B. Gin ("Gin 2nd Decl.") which addresses the consequence of the product by process limitation introduced in the amended claims. Gin 2nd Decl. states that the specified process by which the sustained release matrix is made is novel and unique and the product formed by the process is not disclosed by ant reference cited during the course of the prosecution of the instant application.

C. Claim Rejections – 35 U.S.C. §103 (obviousness)

(i) Claims 1-4, 6-8, 26, 29, 46, 47, 102 and 104-109 stand rejected under 35 USC 103(a) as being obvious over Kigasawa *et al.* (US 4,572,832) in view of Lin *et al.* (J. Controlled Release 2001) and Tisserand (The Art of Aromatherapy, 1977).

Kigasawa is cited for disclosing a soft buccal composition comprising an active, a water-soluble protein, a polyhydric alcohol and a fatty acid ester and/or a carboxyvinyl polymer. Lin is cited for disclosing the effect of ethyl cellulose powders on the release rate of drugs based on particle size and viscosity. Tisserand is cited for disclosing that peppermint oil has a refreshing taste and flavor.

Without acquiescing to the arguments presented in the Office Action, Applicants amend independent claim 1 to specify the steps of the process by which the dosage form specified in the instant claims are produced.

As specified in the instant claims, as amended, the claimed composition is a non-swellable dosage form comprising a sustained release matrix formed by admixing micronized ethylcellulose with a flavoring agent selected from essential oils, constituents of essential oils, and mixtures thereof, "wherein the sustained release matrix is formed by a process *consisting essentially of* admixing the micronized ethylcellulose and the essential oil flavoring agent at room temperature and ambient humidity." No other steps are essential for the formation of the

sustained-release matrix that comprises the dosage form. (emphasis added; See Gin 2nd Decl. ¶ 7).

As stated in Gin 2nd Decl., these process steps are not disclosed in any of the references cited during prosecution of the instant application.

Gin 2nd Decl. further states that this process of manufacture results in the formation of a matrix as follows:

> The terpene structure of essential oils and its solvent effect on ethyl cellulose allows formation of the dough-like substance. This is described as the "soft, wet composition" in various examples in the '781 application. (*See*, Example 1, *et seq.*). Other oils (olive, coconut, palm, etc.), without the terpene structure, are unable to form the dough with ethyl cellulose. The ability to form a dough-like matrix that has sustained release properties is novel and unique and was not previously described in the literature.

(Gin 2nd Decl., ¶ 9)

Kigasawa uses essential oils as a flavorant and not for the formation of a matrix. Its softness is based on use of a water soluble protein, fatty acid ester and/or a carboxyvinlyl polymer. Kigasawa puts together soft wax-like materials to create the consistency of softness and a gelatin-like protein to hold everything together. The polyhydric alcohol is not for the purpose of holding the soft buccal together; this is typically accomplished by the use of an aqueous gelatin (the protein) that is heated and allowed to cool (the "jello" concept). In contrast, the lozenge claimed in the '781 application is not a soft jello/wax-like structure. Ethyl cellulose is a hard polymer that is held together with essential oils and its softness is based on the amount of essential oil used and the ethyl cellulose polymer and the essential oil are admixed to form the lozenge. The instantly claimed process is carried out at room temperature and ambient humidity—it does not use heat and water to dissolve a protein to allow cohesion of the ingredients like Kigasawa. (See Gin 2nd Decl. ¶ 13).

Lin teaches a lozenge where ethyl cellulose forms a "coating" not part of the matrix admixed with essential oils. In contrast, for the claimed product lozenge prepared as disclosed in the '781 application, release of ingredients is not dependent on a coating and release is uniform throughout the lozenge because of the uniform composition. (See Gin 2nd Decl. ¶ 14).

Tisserand merely teaches some pleasant properties of peppermint oil. It does not teach or suggest.

Applicants submit that Kigasawa, Lin and Tisserand, together or in combination do not teach or suggest each and every limitation of the amended claim 1. The process of manufacture is not taught, the sustained release matrix is not disclosed. Further, the matrix (product) formed by the process step specified in claim 1 is not disclosed even as an intermediate in any of the references cited. (See Gin 2nd Decl. ¶ 18).

Therefore, Applicants submit that a prima facie case for obviousness does not exist and respectfully request withdrawal of this ground for rejection.

(ii) Claims 1-4, 6-8, 26, 29, 46, 47, 101, 102 and 104-109 stand rejected under 35 USC 103(a) as being obvious under 35 USC 103(a) over Ventouras (US 6,183,775) in view of Lin et al. (J. Controlled Release 2001), Kulkarni (US 2003/0206942), Tisserand and Gohlke (US 2002/0054917).

Ventouras is cited for disclosing a controlled release lozenge with pleasant organoleptic properties and includes a insoluble film and a swellable polymer.

The lozenges formed by the Ventouras procedure require high compression due to the nature and high amounts of powders present and is thus a tablet forming process (see Ventouras at col. 5 line15 – col. 6 line 24). Ventouras teaches use of a high amount of soluble filler (50 – 99%) and use of a swellable polymer (0.5 to 30%); neither fillers nor swellable polymers are parts of the dosage form according to the pending claims. The claimed dosage form is non-swellable and does not involve use of high compression during its formation. (See Gin 2nd Decl. ¶ 15). The Ventouras patent does not teach forming a soft, pliable, non-tacky, dough-like substance that forms the lozenge.

The deficiencies of Lin and Tisserand are discussed in detail in the previous section.

Kulkarni is cited for disclosing consumable films adapted to dissolve and adhere in the oral cavity. Kulkarni does not disclose essential oils but are cited for disclosing substances that may be delivered by its films.

Kulkarni teaches away from the instant invention. While Kulkarni discloses "water-soluble polymers" the dosage form of claim 1 includes water-insoluble ethyl cellulose. The lozenge specified in claim 1 “erodes” in the mouth and does not dissolve. In contrast, a consumable film according to Kulkarni will result in ingredients being dissolved and ending up

primarily in the stomach rather than being able to work on the oral environment. (See Gin 2nd Decl. ¶ 17).

Gohlke is cited for a general teaching of chewable lozenges. Gohlke's lozenges require high pressure to form a tablet. Due to the nature of ingredients used, the lozenges are not "rock hard" so one can bite into them ("chew") and have a short residence time in the mouth, if chewed. In contrast, high pressure compression is not used in the process specified for formation of the dosage form of the claimed invention. Further, Gohlke does not disclose matrix made with essential oil and ethyl cellulose. (See Gin 2nd Decl. ¶ 16).

Applicants submit that Ventouras, Kulkarni, Gohlke, Lin and Tisserand, together or in combination do not teach or suggest each and every limitation of the amended claim 1. The process of manufacture is not taught, the sustained release matrix is not disclosed. Further, the matrix (product) formed by the process step specified in claim 1 is not disclosed even as an intermediate in any of the references cited. (See Gin 2nd Decl. ¶ 18).

Therefore, Applicants submit that a prima facie case for obviousness does not exist and respectfully request withdrawal of this ground for rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

The Commissioner is hereby authorized to charge any underpayments or credit any over payments in connection with this communication, including any fees for extension of time, which may be required, to Deposit Account No. 50-5132, referencing Attorney Docket No. BEN-00120US. However, an issue fee may not be charged to this account. The Examiner is invited to call the undersigned if such action might expedite the prosecution of this application.

Respectfully submitted,

Dated: November 18, 2011

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